Remarks

Claims 1-16, 18, 21, 23 and 28-43 have been canceled and new claim 44 added. Support for the *att*L and *att*R recombination sites in new claim 44 can be found, *inter alia*, at page 164, paragraph [0508] of the as filed application. Claims 17, 19-20, 22, 24-27 and 44 are pending in the application.

I. The Information Disclosure Statements

The Examiner has indicated that one of the Information Disclosure Statements (IDS) filed August 10, 2006 has not been fully considered because only five of the first twenty publications were deemed by the Examiner to be material to patentability. The Examiner cites 37 C.F.R. §§ 1.56 and 1.98 to support her decision to not consider the remaining references cited in the IDS. (Office Action, page 2.) As a preliminary matter, Applicants believe that the Examiner is referring to the two IDSs filed May 21, 2004.

Applicants find no basis in 37 C.F.R. §§ 1.56 and 1.98 supporting the Examiner's decision to not consider all the references in Applicants' IDSs filed May 21, 2004. Further, Applicants are not aware of any substantive grounds under which the references cited in the IDSs should not be considered. Applicants thus respectfully request that the Examiner consider all of the references cited in the IDSs filed May 21, 2004.

II. Claim Objections

Claims 25 and 26 were objected to for a missing plural and a missing word. (Office Action, page 3.) Applicants appreciate the Examiner pointing out these informalities. As amended herein, claims 25 and 26 have been corrected as suggested by the Examiner.

III. 35 U.S.C. § 112, Second Paragraph

Claims 17, 19-20, 22 and 24-27 stand rejected under 35 U.S.C. § 112, second paragraph, for being indefinite for use of the term "substantially." (Office Action, page 3.) Applicants respectfully disagree but have amended the claim to facilitate prosecution.

As amended herein, independent claim 17 no longer recites the term "substantially."

In view of this amendment, applicants respectfully request reconsideration and withdrawal of the rejection of claims 17, 19-20, 22 and 24-27 under 35 U.S.C. § 112, second paragraph.

IV. 35 U.S.C. § 102(b)

Claims 17, 19-20, 22 and 24-27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Douglas *et al.* (*Human Gene Therapy 12*:401-413 (2001)). (Office Action, page 4.) Applicants respectfully disagree.

In order to anticipate, a single reference must disclose "each and every limitation of the claimed invention." (*Helifix Ltd. v. Blok-Lok, Ltd.*, 208, F.3d 1339, 1346 (Fed. Cir. 2000).)

Using independent claim 17 presented herein for reference, the claimed invention is directed to methods of constructing recombinant viruses. These methods comprise:

(a) providing a first nucleic acid molecule comprising all or a portion of at least one viral genome and at least a first and a second recombination site that do not recombine with each other;

(b) contacting the first nucleic acid molecule with a second nucleic acid molecule comprising a sequence of interest flanked by at least a third and a fourth recombination site

under conditions such that recombination occurs between the first and third recombination site and between the second and fourth recombination site; and

(c) introducing the nucleic acid molecule of step (b) into a cell that packages the nucleic acid molecule of step (b).

Applicants draw the Examiner's attention to Figures 20, 36D and 37A-37C for purposes of illustrating aspects of the invention. Figure 20 shows, in essence, a recombination reaction between a baculoviral vector which contains *att*R1 and *att*R2 sites, referred to as a destination vector. Also shown is a second vector, referred to as an entry clone, which contains a gene of interest (GOI) flanked by *att*L1 and *att*L2 recombination sites. Under suitable circumstances, the *att*R1 site will recombine with the *att*L1 site and the *att*R2 site will recombine with the *att*L2 site, resulting in the gene of interest being introduced into the baculoviral vector.

The process represented in Figure 20 may also be used for other viral vectors. Embodiments of the invention employing lentiviral vectors are represented in Figure 36D and 37A-37C. Figure 36D depicts the pLENTI6/UbC/V5-DEST vector which comprises a portion of a viral genome, a packaging signal (ψ), and *att*R1 and *att*R2 recombination sites. When an entry clone, such as the one depicted in Figure 20, is contacted with the destination vector, as above, the *att*L1 site recombines with the *att*R1 site and the *att*L2 site recombines with the *att*R2 site resulting in the insertion of the gene of interest into the destination vector. The destination vector may then be transfected into a cell along with plasmids such as those depicted in Figure 37A-37C for packaging.

Douglas *et al.* does not disclose, *inter alia*, a recombination reaction as recited in independent claim 17. Therefore, Douglas *et al.* does not disclose each and every limitation of

independent claim 17 or any of dependent claims 19-20, 22, 24-27 and 44. Thus, Douglas *et al.* does not anticipate claims 17, 19-20, 22, 24-27 and 44.

In view of these remarks, applicants respectfully request reconsideration and withdrawal of the rejection of claims 17, 19-20, 22 and 24-27 under 35 U.S.C. § 102(b).

Conclusion

Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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